OLYMPUS

K123365

MAR 0 1 2013

510(k) SUMMARY

OLYMPUS LTF-190-10-3D, ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE
MAJ-Y0154, 3D PROCESSOR
OLYMPUS CV-190, EVIS EXERA III VIDEO SYSTEM CENTER

November 12, 2012

1 General Information

- Applicant:

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
Establishment Registration No: 8010047

- Official Correspondent:

Sheri L. Musgnung
Regulatory Affairs & Quality Assurance
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- Manufacturer:

(LTF-190-10-3D, MAJ-Y0154)
OLYMPUS MEDICAL SYSTEMS CORP.
Hinode Plant
34-3 Hirai, Hinode-cho, Nishitama-gun,
Tokyo, 190-0182, Japan
Establishment Registration No.:3003637092

(CV-190)
SHIRAKAWA OLYMPUS CO., LTD.
3-1,
Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
Nishishirakawa-gun, Fukushima, Japan 961-8061
Establishment Registration No: 3002808148

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2 Device Identification

- Device Trade Name: OLYMPUS LTF-190-10-3D ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE 3D PROCESSOR

  MAJ-Y0154 3D PROCESSOR

  OLYMPUS CV-190 EVIS EXERA III VIDEO SYSTEM CENTER

- Common Name: ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE
  3D PROCESSOR
  EVIS EXERA III VIDEO SYSTEM CENTER

- Regulation Number: 21 CFR 884.1720
  21 CFR 876.1500

- Regulation Name: Gynecologic laparoscope and accessories
  Endoscope and Accessories

- Regulatory Class: II

- Classification Panel: General and plastic surgery,
  Obstetrics/Gynecology
  Gastroenterology and urology

- Product Code: FGB, HET, GCJ, and NWB

3 Predicate Device Information

Subject Device (Part of this submission)	Predicate Device	PD's 510(k) No.
OLYMPUS LTF-190-10-3D ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE (Hereinafter referred to as LTF-190-10-3D)	LTF-Y0009 3D Laparo-Thoraco Videoscope	K102379
	LTF-S190-10 ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE	K111425
MAJ-Y0154 3D PROCESSOR (Hereinafter referred to as MAJ-Y0154)	MAJ-Y0041 3D Video Mixer	K102379
OLYMPUS CV-190 EVIS EXERA III VIDEO SYSTEM CENTER (Hereinafter referred to as CV-190)	CV-190 EVIS EXERA III VIDEO SYSTEM CENTER	K112680
	OTV-S190 VISERA ELITE VIDEO SYSTEM CENTER	K111425

4 Device Description

The subject system is intended for endoscopy and endoscopic surgery with three-dimensional view of endoscopic images and the system is mainly composed of following devices.
- LTF-190-10-3D (ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE)
- MAJ-Y0154 (3D PROCESSOR)
- CV-190 (EVIS EXERA III VIDEO SYSTEM CENTER)

The ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-190-3D is a flexible video endoscope used for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs.

The subject device, LTF-190-3D is utilized with the MAJ-Y0154, 3D Processor and the CV-190, EVIS EXERA III VIDEO SYSTEM CENTER. The connection of the devices enables the system for endoscopic observation in 3D view of the image.

The 3D video observation of this system is implemented with following process.

The captured signals from two CCDs which correspond to left and right eye incorporated in the distal end of the subject LTF-190-10-3D are transferred to the MAJ-Y0154 via two CV-190s. Both CV-190s convert the captured signals into video image signals, and transmits them to the MAJ-Y0154.
The MAJ-Y0154 converts the video image signals into 3D video signal and transfers it to the LMD-2451MT, (K113203). On the LMD-2451MT, 3D video image is displayed as passive stereo type which has different polarizing angle in the left and right; therefore, the 3D glasses for LMD-2451MT are required to obtain 3D video image.

5 Indications for Use

LTF-190-10-3D

This instrument is intended to be used with Olympus video system center, light source, documentation equipment, 3D processor, monitor, hand instruments, electrosurgical unit and other ancillary equipment for endoscopy and endoscopic surgery. This instrument is indicated for use within the thoracic and abdominal cavities including female reproductive organs.

This instrument must not be used for observation or treatment of the heart and must not contact the heart or any area near the heart. In addition, this instrument must not come into contact with any device or therapeutic accessory that contacts the heart or any area near the heart.

CV-190

This video system center is intended to be used with Olympus camera heads, endoscopes, light source, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

MAJ-Y0154

This 3D processor is intended to be used with 3D videoscope and video system center for 3D observation.

6 Comparison of Technological Characteristics

The OLYMPUS LTF-190-10-3D, MAJ-Y0154, OLYMPUS CV-190 are basically identical to the predicate device in intended use, and similar in specifications.

The subject LTF-190-10-3D is nearly identical to the predicate LTF-Y0009. It has identical spefications to the predicate device except for; (1) addition information in a memory, (2) NBI observation in 3D view and (3) addition of sterilization method.

Compared to the predicate device, the MAJ-Y0154 incorporates the following features: (1) Communication with the video system center, (2) 3G-SDI image signal output, (3) Recognition of synchronization of input image signals, (4) Menu, (5) Automatic switching of 2D/3D view of endoscopic image, (6) Switching of 2D/3D output for recording .

The subject CV-190 has almost the same in design and function to its predicate CV-190 except for following features: (1)Link between the video system centers. (2)Synchronization with the 3D processor MAJ-Y0154 (GenLock). (3)Communication with the 3D processor MAJ-Y0154.

7 Summary of non-clinical testing

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

The software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The device software is considered a "Moderate Level of Concern."

The following bench tests were conducted to demonstrate the substaintal equivalence and safety and effectiveness of the subject devices:

- Mechanical durability testing
- Electrical safety testing
- Electromagnetic compatibility testing
- Thermal safety testing
- Bench testing to support promotional claims

The following standards have been applied to the subject system :

- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-2-18
- IEC 60601-1-2
- ISO 14971
- ISO 10993-7
- ANSI/AAMI/ISO 11135-1

8 Conclusion

When compared to the predicate device, the OLYMPUS LTF-190-10-3D, MAJ-Y0154 and OLYMPUS CV-190 do not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device and therefore is Substantially Equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 1, 2013

OLYMPUS MEDICAL SYSTEMS CORP.
% Ms. Sheri L. Musgnung
Regulatory Affairs & Quality Assurance
Olympus Corporation of the Americas
3500 Corporate Parkway, P.O. Box 610
CENTER VALLEY PA 18034-0610

Re: K123365
Trade/Device Name: OLYMPUS LTF-190-10-3D ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE
MAJ-Y0154, 3D PROCESSOR
OLYMPUS CV-190, VIDEO SYSTEM CENTER
Regulation Number: 21 CFR§ 884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: HET, GCJ, NWB, FGB
Dated: January 29, 2013
Received: January 30, 2013

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123365

Device Name:

OLYMPUS LTF-190-10-3D, ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE

Indications For Use:

This instrument is intended to be used with Olympus video system center, light source, documentation equipment, 3D processor, monitor, hand instruments, electrosurgical unit and other ancillary equipment for endoscopy and endoscopic surgery. This instrument is indicated for use within the thoracic and abdominal cavities including female reproductive organs.

This instrument must not be used for observation or treatment of the heart and must not contact the heart or any area near the heart. In addition, this instrument must not come into contact with any device or therapeutic accessory that contacts the heart or any area near the heart.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123365

Indications for Use

510(k) Number (if known): K123365

Device Name: MAJ-Y0154, 3D PROCESSOR

Indications For Use:

This 3D processor is intended to be used with 3D videoscope and video system center for 3D observation

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and Urological Devices

510(k) Number K123365

Indications for Use

510(k) Number (if known): K123365

Device Name: OLYMPUS CV-190, VIDEO SYSTEM CENTER

Indications For Use:

This video system center is intended to be used with Olympus camera heads, endoscopes, light source, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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